U.S. Application No. 09/990,773 Inventor: Hajizadeh, K.

Attorney Docket No. 3873 P 011

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SPECIFICATION AMENDMENT

In the "Brief Description of the Drawings," please amend the corresponding paragraphs as follows:

[Page 5, line 22, through page 6, line 4]

Figure 1 is a side perspective view of one embodiment of a test device in accordance with the teachings of the present invention;

Figure 2 is a side perspective top view of another embodiment of a test device in accordance with the invention;

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Figure 3 is a top schematic <u>side</u> view of another embodiment of a test device made in accordance with one aspect of the invention; and,

Figure 4 is a side perspective view of still another embodiment of the test device made in accordance with the invention.

In the "Detailed Description of the Invention," please amend the corresponding paragraphs as follows:

[Page 11, lines 15-19]

In a preferred embodiment, the test strip 12 is may be affixed to a strip support (e.g., support 313, as shown in FIGURE 4) of a sufficiently rigid, impervious and non-reactive material such as polystyrene, polyvinyl chloride, and polyethylene terephthalates. Typically, the strip support is hydrophobic in nature to ensure that the maximum amount of test sample is directed for analysis. In a preferred embodiment, the strip support includes at least one layer of an impervious material.



[Page 13, lines 6-17]

The conjugate pad comprises any absorbent material or suitable support for the labeled antibodies, such as a plastic filter bed in glass fiber, polyester, plastic bonded glass fiber, and other



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nonwoven materials, as examples. The conjugate pad lies in direct fluid communication with the test strip. A spacer pad 28 may optionally be used between the conjugate pad 22 and the digestive pad 20.

An alternative embodiment includes a filter pad 24 in fluid communication with the digestive pad 20, opposite the <u>spacer pad 28 and the</u> conjugate pad 22. Homogenized sample may be applied to the filter pad 24, an absorbent pad of a material that receives the fluid sample and allows it to flow into the conjugate pad 22. The filter pad 24 may also function to remove larger particles that may interfere with the assay. The filter pad 24 may comprise any suitable material such as gauze, cellulose, cellulose acetate, other polyesters, and other porous membranes, for example. Alternatively, the sample may be filtered in a separate step prior to its introduction to the digestive pad.

[Page 14, lines 15-19]

An additional pad may be needed to separate digestive pad from the conjugate pad. In another embodiment of the invention, the test strip may have a single pad impregnated with PK enzyme, serving both as the digestive pad and the filter pad. Though optional, a spacer pad 228 (e.g., see spacer pad 28 of FIGURE 1) may be disposed between the digestive pad 220 and the conjugate pad 222 to allow for more complete digestion of the normal prion before it reaches the conjugate pad.

[Page 16, lines 2-11]

The PrP^{SC} may also be detected in biological samples and animal feeds by use of a testing system comprising (a) proteinase-K immobilized on a support external to the test strip, for digesting the nonpathogenic form of prion protein in a separate wet analysis conducted prior to introducing the homogenized sample to the test strip; and (b) a test strip that analyzes the enzymatically treated sample for the presence and concentration of PrP^{SC}. Shown in Figure 4 is a test device 310, having a test strip 312 and an impervious strip support 313, that is suitable for use in this aspect of the



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invention. Test device 310 includes a conjugate pad 322, a detection region 326, and a test line 318. Optionally, the test device may also include one or more of a filter pad 324, a spacer pad 328, a control line 330, and a wicking pad 329. The test system is used with sample prepared as described above.